

REMARKS

Applicants respectfully request reconsideration of the above-identified application in view of the foregoing amendment and in view of the reasons that follow.

Status of the claims

Claims 1-20 were originally filed in the above-identified application and were the subject of the Restriction Requirement of September 9, 2003.

In response to the Restriction Requirement, Applicants canceled claims 1-20, added new claims 21-40, and elected, with traverse, new claims 21-27, 31, and 32, drawn to substantially the same invention as the claims of Group XVII (original claims 1-6, 12-15, and 19, now canceled). Response of October 9, 2003.

Claims 21-28, 31, and 32 were examined, and claims 29, 30 and 33-34 were withdrawn from consideration by the Examiner, in the Office Action of February 9, 2004.

Claim 21 was amended in the Response of May 4, 2004.

Claims 29, 30, and 33-40, claims which were previously withdrawn from consideration are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 21 and 28 are currently being amended. Claim 21 has been amended to recite, "and having decreased expression in leukemia, lymphoma and prostate tumor cells," to clarify the claimed invention. Claim 28 has been amended to recite "and encoding a polypeptide that has decreased expression in leukemia, lymphoma and prostate tumor cells." Exemplary support for these amendments is found, for example, on pages 32-33 of the specification.

Claims 41 and 42 are currently being added. Exemplary support for these newly added claims is found on pages 23 and 24 of the specification. Claims 41 and 42 are added to more clearly define claim scope.

Claims 21-28, 31, 32, 41, and 42 are pending in the application.

Rejection under 35 U.S.C. § 119(e) relating to priority

The Examiner asserts that the instant specification has been rejected for a lack of utility and lack of enablement. Therefore, the Examiner asserts that full benefit of priority is not provided.

As discussed below, the specification possesses both utility and enablement. Thus, because SEQ ID NOS: 17 and 44 of the present application correspond to SEQ ID NOS: 4 and 19 of the priority document, U.S. Provisional Application No. 60/119,365, the present claims are entitled to the filing date of the priority document.

Rejection under 35 U.S.C. § 101

Claims 21-28, 31, and 32 were rejected under 35 U.S.C. § 101, as allegedly lacking utility. Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

MPEP § 2107(II) states that “an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention.” Additionally, an Applicant needs to “establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.” On the basis of the above recited MPEP sections, the original specification and the attached publication, Applicants argue that the subject matter of the present application possesses specific and substantial utility as required under 35 U.S.C. § 101.

The specification provides a utility for the claimed polypeptides and nucleic acid sequences in the diagnosis and treatment of leukemia, lymphoma and prostate cancer

The specification provides a utility for the claimed polypeptides and nucleic acid sequences. Page 22 of the specifications states that the claimed polypeptide and

polynucleotides are useful for the diagnosis, treatment, or prevention of cell proliferative disorders including cancer. Additionally, on pages 32-33 of the specification, it states that the claimed polypeptide is useful for treating diseases associated with decreased expression of the claimed polypeptide, such as prostate cancer, lymphoma and leukemia.

Furthermore, attached herewith as Exhibit 1 is a sequence alignment between SEQ ID NO: 17 and TMEPAI showing that the two sequences share 99% identity. Attached as Exhibit 2 is a document which shows that TMEPAI is an alias for PMEPA1. Also, attached herewith as Exhibit 3 is Xu et al., Cancer Research (2003) 63:4299-4304, which describes a study of the expression of PMEPA1 in prostate tumor cells. Xu et al. found decreased expression of PMEPA1 in prostate tumor cells and determined that PMEPA1 has cell growth inhibitory effects when overexpressed in androgen-dependent or independent CaP cells. *See, e.g.*, Table 1 and page 4303 of Xu et al. Additionally, Rae et al., Molecular Carcinogenesis (2001) 32:44-53 (Exhibit 4) reports that STAG1/PMEPA1 expression was barely detectable in leukemia and lymphoma samples. *See, e.g.*, abstract. Therefore, the claimed polypeptides and nucleic acids are useful for diagnosing and treating prostate cancer, leukemia and lymphoma.

In light of the above identified uses for the claimed protein sequence compositions, Applicants argue that the subject matter of the claimed invention discloses at least “one credible assertion of specific and substantial utility” and thus, satisfies the requirements of 35 U.S.C. §101. Therefore, Applicants respectfully request that this rejection be withdrawn and the present claims allowed.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

Claims 21-28, 31, and 32 were also rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabling for the full scope of the claimed invention. Applicants traverse the rejection and respectfully request reconsideration and withdrawal of the rejection.

The Examiner asserts that because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. As discussed above, the present specification satisfies the requirements of 35 U.S.C. § 101.

A person of ordinary skill in the art would know how to make and use the claimed polypeptides and polynucleotide sequences

The Examiner further asserts that Applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonable correlated with the scope of the claims. Applicants respectfully disagree. The specification provides sufficient guidance to enable a person of ordinary skill in the art to make and use the claimed invention. First, Applicants have deleted the term “naturally occurring” from the claims. Applicants have also amended claim 21(b) to recite that the “naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:17” has “decreased expression in leukemia, lymphoma and prostate tumor cells.” Additionally, Applicants have amended claim 28(b) to recite “a polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:44, and encoding a polypeptide that has decreased expression in leukemia, lymphoma and prostate tumor cells. Finally, Applicants note that the claims do not recite “biologically active variants,” as indicated by the Examiner on page 18 of the outstanding Office Action.

Furthermore, Table 2 shows structural features of SEQ ID NO: 17, including potential motifs, homologous sequences, and methods, algorithms, and databases used for the analysis of the polypeptide. This information includes “signature sequence” information which shows that SEQ ID NO: 17, has a specifically defined signal peptide region, a glycosaminoglycan attachment site and a transmembrane region. Table 2 also identifies potential phosphorylation and glycosylation sites. A person of ordinary skill in the art would know that the claimed polypeptide would need to maintain at least some of the regions disclosed in Table 2. The knowledge of a person of ordinary skill in the art, along with the guidance of Table 2 and the rest of the specification, would enable one of ordinary skill in the art to make and use the claimed polypeptide.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claims 21-28, 31, and 32 were rejected as allegedly failing to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

As discussed above, Applicants have deleted the term “naturally occurring” from the claims. Applicants have also amended claim 21(b) to recite that the “naturally occurring amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:17” has “decreased expression in leukemia, lymphoma and prostate tumor cells.” Additionally, Applicants have amended claim 28(b) to recite “a polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:44, and encoding a polypeptide that has decreased expression in leukemia, lymphoma and prostate tumor cells. Finally, Applicants note that the claims do not recite “biologically active variants,” as indicated by the Examiner on page 18 of the outstanding Office Action. Therefore, the claims recite sufficient structural and functional language, which is fully supported by the disclosure of the specification, so that a person of ordinary skill in the art would know that Applicants had possession of the claimed invention at the time of filing.

Furthermore, the specification describes common attributes and characteristics that identify members of the genus. As discussed above, Table 2 shows structural features of SEQ ID NO: 17, including potential motifs, homologous sequences, and methods, algorithms, and databases used for the analysis of the polypeptide. This information includes “signature sequence” information which shows that SEQ ID NO: 17, has a specifically defined signal peptide region, a glycosaminoglycan attachment site and a transmembrane region. Table 2 also identifies potential phosphorylation and glycosylation sites.

Rejections under 35 U.S.C. § 102

Claims 21, 22, 24-28, 31, and 32 were rejected as allegedly being anticipated by U.S. Patent Pub. No. 2003/0027998, filed March 2, 2001 and published February 6, 2003 and

Srivastana et al. (U.S. Patent No. 6,566,130), filed May 20, 2003. Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

The effective dates of the cited U.S. Patent Publication and U.S. Patent are clearly after the priority date of 60/117, 365, filed February 9, 1999, to which the instant application claims priority. Since the present specification possesses both utility and enablement as described above, the specification is entitled to the priority date of February 9, 1999. Therefore, U.S. Patent Pub. No. 2003/0027998 and U.S. Patent No. 6,566,130 are not valid prior art against the present application.

Newly Added Claims 41 and 42

Newly added claims 41 and 42 meet the requirements of 35 U.S.C. §§ 112 and 101 for the reasons described above. Similarly, newly added claims 41 and 42 are free of the prior art for the reasons discussed above.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 10/26/04

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